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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/620,840 | 07/16/2003 | Karen Duff | 1310.002US1 | 8787 |
| 21186 | 7590 | 02/22/2006 | EXAMINER | |
| SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH | | | CHEN, SHIN LIN | |
| 1600 TCF TOWER | | | ART UNIT | PAPER NUMBER |
| 121 SOUTH EIGHT STREET | | | 1632 | |
| MINNEAPOLIS, MN 55402 | | | | |

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------|------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/620,840 | DUFF, KAREN | |
| | Examiner Shin-Lin Chen | Art Unit 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) ____ is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: ____ . |

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, 7 and 10-12, drawn to a transgenic mouse comprising a human genomic DNA encoding human tau and six isoforms of human tau are expressed and a method for expression of human tau in a mouse by preparing said transgenic mouse, classified in class 800, subclasses 18 and 21.
 - II. Claims 4-6, 8, 9 and 13-17, drawn to a transgenic mouse comprising a mutated human genomic DNA sequence encoding mutated human tau, and a method for expression of mutated human tau in a mouse by preparing said transgenic mouse, classified in class 800, subclasses 18 and 21.
 - III. Claim 18, drawn to a method of using a transgenic mouse to screen for an agent that reduces or inhibits a neurodegenerative disorder by using a transgenic mouse comprising a human genomic DNA encoding tau, classified in class 800, subclass 3.
 - IV. Claim 19, drawn to a method to screen for an agent that reduces or inhibits abnormal tau formation by administering said agent to an organotypic slice culture comprising cells obtained from the brain of the transgenic mouse of claim 1, classified in class 435, subclass 40.5.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are distinct from each other because they are drawn to transgenic mice having DNA sequences that differ in chemical structures and biological functions: wild type human genomic sequence encoding tau vs mutated human DNA sequence encoding mutated tau.

The transgenic mice of group I and II differ phenotypically and physiologically because the

DNA used to make said transgenic mice are different. Thus, groups I and II require separate search and are patentably distinct from each other.

Groups I-II and group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transgenic mouse can be used to produce a recombinant protein instead of using said transgenic mouse for screening an agent. They have different classifications and require separate search. Thus, groups I-II and group III are patentably distinct from each other.

Groups I-II and group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transgenic mouse can be used to produce a recombinant protein instead of using said transgenic mouse to produce an organotypic slice culture for screening an agent. They have different classifications and require separate search. Thus, groups I-II and group IV are patentably distinct from each other.

Group III and group IV are distinct from each other because they are drawn to materially different methods that differ at least in objectives, method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. They are drawn to different scientific considerations: a method of using a transgenic mouse to screen for an agent that

reduces or inhibits a neurodegenerative disorder by using a transgenic mouse and a method to screen for an agent that reduces or inhibits abnormal tau formation by administering said agent to an organotypic slice culture. Further, groups III and IV have different classifications and require separate search. Thus, groups III and IV are patentably distinct from each other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.



SHIN-LIN CHEN
PRIMARY EXAMINER